



FINAL DOCUMENT

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A handwritten signature in black ink, which appears to read 'Abraao Carvalho', is written over a light blue, textured background.

Abraao Carvalho, GHTF Chair

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**IMPLEMENTATION OF RISK MANAGEMENT PRINCIPLES AND ACTIVITIES WITHIN A
QUALITY MANAGEMENT SYSTEM**

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Implementation of risk management principles and activities within a quality management system

1. Introduction:

Medical device manufacturers are generally required to have a quality management system as well as processes for addressing device related risks. These processes for managing risk can evolve into a stand-alone management system. While manufacturers may choose to maintain these two management systems separately, it may be advantageous to integrate them as it could reduce costs, eliminate redundancies, and lead to a more effective management system.

This document is intended to assist medical device manufacturers with the integration of a risk management system or risk management principles and activities into their existing quality management system by providing practical explanations and examples.

A basic understanding of quality management system requirements and a basic knowledge of quality management system terminology are assumed in this guidance document.

This document is based on general principles of a quality management system and general principles of a risk management system and not on any particular standard or regulatory requirement. This document also:

- § Has general applicability to quality management systems for manufacturers providing medical devices;
- § Discusses risk management related to medical device safety, rather than financial or other business risks;
- § Does not suggest a particular method of implementation; and
- § Does not include requirements to be used as the basis of regulatory inspection or certification assessment activities

The scope of the medical device manufacturer's quality management system will define the applicability and extent of implementing risk management principles and activities. Processes required by the quality management system and performed by suppliers to the manufacturer are the responsibility of the manufacturer. Risk management activities relating to any process within the quality management system are ultimately the responsibility of the manufacturer.

An effective quality management system is essential for ensuring the safety and performance of medical devices. A well-defined quality management system includes safety considerations in specific areas. Given the importance of safety, it is useful to identify some key activities that specifically address safety issues and ensure appropriate input and feedback from these activities into the quality management system. The degree to which safety considerations are addressed should be commensurate with the degree of the risk and the nature of the device. Some devices present relatively low risk or have well-understood risks with established methods of risk control, while others push the state-of-the-art.

Risk management principles should be applied throughout the life cycle of medical devices and used to identify and address safety issues. In general, risk management can be characterized by phases of activities. The following discussion is one example of how these phases can be described. The first phase can be the determination of levels of risk that would be acceptable in the device. Manufacturers should have a procedure or policy to determine risk acceptability criteria. These risk acceptability criteria may come from an analysis of the manufacturer's own experience with similar medical devices or research on what appears to be currently accepted risk levels by regulators, users, or patients, given the benefits derived from diagnosis or treatment with the device. Risk acceptability criteria generally should be reflective of state-of-the-art in controlling risks.

The second phase can be risk analysis. This phase starts with identifying hazards that may occur due to characteristics or properties of the device during normal use or foreseeable misuse. After hazards are identified, risks are estimated for each of the identified hazards, using available information.

In the third phase, the estimated risks are compared to the risk acceptability criteria. This comparison will determine an appropriate level of risk reduction, if necessary. This is called risk evaluation. The combination of risk analysis and risk evaluation is called risk assessment.

The fourth phase can be composed of risk control and monitoring activities. The manufacturer establishes actions, i.e. risk control measures, intended to eliminate or reduce each risk to meet the previously determined risk acceptability criteria. Within the limits of feasibility, one or more risk control measures may be incorporated in order to achieve this end. Risk control activities may begin as early as design input and continue through the design and development process, manufacturing, distribution, installation, servicing and throughout the medical device life cycle.

Some regulatory schemes prescribe a fixed hierarchy of risk control measures that should be examined in the following order:

- § Inherent safety by design;
- § Protective measures in the device or its manufacture;
- § Information for safety, such as warnings, etc.

Throughout the life cycle of the device the manufacturer monitors whether the risks continue to remain acceptable and whether any new hazards or risks are discovered. Information typically obtained from the quality management system, for example, production, complaints, customer feedback, should be used as part of this monitoring. If at any time, a risk is determined to be unacceptable, the existing risk analysis should be reexamined and appropriate action taken to meet the risk acceptability criteria. If a new hazard is identified, four phases of risk management should be performed.

These activities can be performed within the framework of the quality management system.

1.1. Purpose

This guidance document is intended for educating the medical device sector. However, it is not intended to be used to assess or audit compliance with regulatory requirements.

1.2. Scope

This document discusses and supports the implementation and integration of a risk management system within a medical device manufacturer's quality management system and provides practical explanations and examples.

2. Definitions:

Harm

physical injury or damage to the health of people, or damage to property or the environment
[ISO/IEC Guide 51:1999, definition 3.1]

Hazard

potential source of harm
[ISO/IEC Guide 51:1999, definition 3.5]

Residual risk

risk remaining after protective measures have been taken.
[ISO/IEC Guide 51:1999, definition 3.9]

Risk

combination of the probability of occurrence of harm and the severity of that harm
[ISO/IEC Guide 51:1999, definition 3.2]

Risk analysis

systematic use of available information to identify hazards and to estimate the risk
[ISO/IEC Guide 51:1999, definition 3.10]

Risk assessment

overall process comprising a risk analysis and a risk evaluation
[ISO/IEC Guide 51:1999, definition 3.12]

Risk control

process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels
[ISO 14971:2000, definition 2.16]

Risk evaluation

judgment, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society
[NOTE Based on ISO/IEC Guide 51: 1999, definitions 3.11 and 3.7]

Risk management

systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk
[ISO 14971:2000, definition 2.18]

3. General:

3.1. Documentation

Documents or records resulting from risk management activities such as risk management procedures, reports, etc. may be maintained or referenced in either a risk management file or other appropriate files (e.g., Design History File, Technical File/Technical Documentation, Design Dossier, Device Master Record, Device History Record, or Process Validation files).

The manufacturer should consider the benefits of integrating the risk management procedures, documents and records directly into the quality management system procedures, documents, and records. The advantage of this could be a single document control system, ease of use and review, accessibility, retention, etc. If a manufacturer chooses to integrate the risk management system into the quality management system, the risk management file should contain references or an index of where the risk management requirements are satisfied.

Document controls, including document change controls, for risk management system documentation should be the same as the controls for quality management system documentation. This documentation can be in any form or type of medium.

3.2. Internal and External Communication

Within the quality management system, consideration needs to be given to internal and external communication throughout the entire medical device life-cycle. The type and depth of the communication should be appropriately tailored to the target audience.

Internal communication is necessary for all appropriate personnel to be aware of the remaining risks even after implementing risk control measures. Annex A provides an example of a risk chart for communicating internal risk management activities.

External communication methods such as warning labels, user manuals, advisory notices, etc., should also be utilized to communicate necessary risk information.

4. Management Responsibilities:

Top management has a responsibility to incorporate risk management into the organization. This includes establishing risk management policies to ensure effective implementation of risk management principles and activities.

Objectives relating to device safety should be a major part of the overall quality objectives of the manufacturer. Management should also ensure that as part of quality planning, planning for risk management activities is carried out in order to meet these objectives. These activities should include:

- Establishment of risk acceptability criteria
- Risk analysis
- Risk evaluation
- Risk control and monitoring

Management is responsible for providing sufficient resources to carry out risk management activities.

Management should ensure that responsibilities and authorities for risk management activities are defined and assigned to qualified personnel, including those related to monitoring data from production and post-production.

Manufacturers should plan and perform internal quality audits to verify whether risk management activities and related results comply with planned and established procedures. The internal audits should ensure the continued effectiveness of the risk management system.

Management reviews of the quality management system should include information from internal quality audits including risk management activities and related results, where appropriate.

5. Outsourcing

A manufacturer may outsource processes (e.g. sterilization, tooling, coating processes, testing, design, manufacturing) or products (components, subassemblies or entire devices) and must maintain control over these outsourced processes and products. The manufacturer is responsible for incorporating appropriate risk management activities for these processes and products by planning and by ensuring risk control measures are appropriately applied. Before the approval and implementation of a change to any outsourced process or product, the manufacturer should:

- Review the change;
- Assess if new risks have been discovered; and,
- Determine if current and/or new individual residual risks and/or the overall risk is acceptable according to the predetermined existing acceptability criteria.

If there are any risk control measures applied to outsourced process or products, the risk control measures and their importance should be documented within the purchasing data or information and clearly communicated to the supplier.

6. Planning:

Risk management planning needs to span the entire life cycle of a medical device. A separate risk management plan may not be necessary if the manufacturer adequately addresses risk management within the quality management system planning activities.

7. Design and Development:

Design and development of a medical device is an evolutionary process, embracing many engineering and management practices. Integral to activities associated with this process are the identification and control of risks. Risk controls can be influenced by technical and business feasibility considerations, as well as considerations of device functionality and

associated benefits. The objective of risk management is rarely to eliminate all risk, but rather to reduce risk to an acceptable level while maintaining feasibility and functionality.

Risk management activities should begin as early as possible in the design and development phase, when it is easier to prevent problems rather than correcting them later. For each identified hazard, the risk in both normal and fault conditions is estimated. In risk evaluation, the manufacturer decides whether risk reduction is needed. The results from this risk evaluation such as the need for risk control measures then become part of the design input.

Risk control measures are part of the design output and are evaluated during design verification. This design input/output/verification cycle will iterate and continue throughout the overall design control process until the residual risks have been reduced to an acceptable level and can be maintained at an acceptable level. The overall effectiveness of risk control measures is confirmed during design validation.

Relying exclusively on design and development processes to control risk is not sufficient. Even the best design and development processes can fall short of ensuring error free design output.

After release of the device to market, risk management activities should be linked to quality management processes, for example, production and process controls, corrective and preventive actions (CAPA), servicing and customer feedback.

Design and development activities targeted at controlling risks should be supported by documentation. This documentation should relate the design activities to identified risks in a way that provides objective evidence that the nature and extent of the design control is reasonable and appropriate to the degree of risk.

The flowchart depicted in Annex B shows a synopsis of the risk management activities overlaid on the general design and development process as defined within a quality management system.

7.1. Design and development planning

Design and development planning should ensure that coordination of risk management activities is conducted during design and development. Design and development planning should identify:

- The inter-relationship(s) between appropriate risk management activities and design and development activities; and,
- The needed resources, including appropriate expertise required to ensure sufficient coverage of potential safety concerns.

7.2. Design and development input

Design and development inputs for a device are captured in one or more documents intended to be the foundation for subsequent design and development activities. Design and development inputs include adequate consideration of intended use and functional, performance, safety and regulatory requirements.

Risk control measures are one output from risk management activities, which should feed into the design and development process.

Risk analysis consists of identifying hazards and the potential harms due to those hazards and estimating the risks of those harms occurring. Hazard identification starts with consideration of the medical device's intended use, its characteristics and its environment. Risk-related data from post-production information for the generic type of device should be considered if it is available. In addition, risk-related information on the manufacturing methods to be used in the production of the device should be considered. This normally results in a preliminary list of known and foreseeable hazards. Such hazards may be found in relevant standards or other data sources such as vigilance databases, independent product test reports, etc.

The identified hazards may produce several harms, as well as, one harm may come from several hazards. The probability of occurrence of the harm and its severity need to be determined. (See Annex A). Risks from these hazards are estimated and evaluated against previously established acceptability criteria to determine whether risk controls are needed.

Any proposed changes to identified design characteristics, specifications, and/or risk control measures and their associated hazards from the current risk analysis must be carefully evaluated with respect to continued safety and specified performance of the device before actual implementation.

If the device is intended to be used in combination with, or installed with, or connected to another medical device or equipment, then hazards and risk control measures should be evaluated for each device individually as well as the system or combination as a whole.

When establishing design and development inputs, the need for risk control measures should be considered. When risk control measures are determined to be necessary and are initially defined, these become an output as part of the iterative cycle.

7.3. Design and development outputs

Risk control measures identified during the input phase must be designed and incorporated into the design and development output. These risk control measures will have to be evaluated as to their feasibility.

Design and development outputs are generally of three types. The first type includes specification of the characteristics of the medical device, as well as those essential for its safe and proper use. The second type of design output relates to requirements for purchasing, production, handling, distribution and servicing. The third type includes medical device acceptance criteria. All types may include information essential for safe and proper use. Risk control measures may fall into any of these categories. Table 1 shows examples of each type of risk control measure.

Table 1

| Design and development output type | Examples of risk control measures |
|--|---|
| medical device characteristics including those essential for its safe and proper use | <ul style="list-style-type: none"> • Compliance with IEC 60601 • Over-temperature alarm • Information related to any residual risk |

| | |
|---|--|
| | <p>(e.g. warning label on device, operators manual, or service manual)</p> <ul style="list-style-type: none"> • Redundant power source on a life-support device • Interlock switch on access door of an x-ray cabinet • Watchdog timer (in a microprocessor-based device) • User training |
| requirements for purchasing, production, handling, distribution and servicing | <ul style="list-style-type: none"> • Special quality requirements in contracts • Imposing stringent process controls • Mandatory part replacements in planned maintenance service intervals for process equipment or the medical device itself • Limitation of lot sizes • Environmental requirements such as temperature, pressure, humidity, etc. |
| medical device acceptance criteria | <ul style="list-style-type: none"> • Torque specification for a threaded fastener • Dimensional tolerances for a vacuum line fitting • Contamination levels or sterility requirements for a device or accessory • Electrical safety performance limits (e.g., leakage current, insulation strength) |

Design outputs will include the specific risk control measures and where those risk control measures will be applied.

During the design and development process, when inherent safety and/or design for protective measures are not possible or practical, additional risk control measures such as labeling, training and residual risk communication may be necessary design outputs. These risk control measures should apply to the medical device life-cycle.

7.4. Design and development review

Design and development reviews should determine if any individual residual risks as well as any overall residual risk are adequately communicated to appropriate individuals including users. These reviews should determine the validity of risk/benefit decisions related to the acceptance of the overall residual risk. Reviewers should have the necessary competence to assess design decisions concerning risk acceptability.

Design review procedures should define risk review tasks that should be performed at appropriate stages of design and development. Design and development reviews should assess, for example:

- Whether all hazards have been identified, risk properly assessed and potential risk control measures identified.
- The effectiveness of risk control measures for individual risks.

- If design validation activities effectively assessed the overall residual risk associated with the use of the device by the intended user.
- Whether new risk-related issues identified during the design transfer process were controlled and verified.

7.5. Design and development verification

Design and development verification should generate objective evidence that identified risks were addressed, risk control measures were implemented as necessary, and risk control measures were verified to be effective so that the end result meets the defined acceptability criteria.

Procedures should define appropriate analytical techniques and test methods related to safety requirements. Procedures should ensure traceability between identified hazards, risk control measures, medical device design and development requirements, test plans, and test results.

Annex C is an example of a risk management summary in a table format, which also demonstrates traceability.

7.6. Design and development validation

Validation confirms the medical device meets user needs, intended uses, and the overall residual risk meets the overall acceptability criteria. To ensure risk control measures are adequately addressed in the validation plan, the plan should include sufficient numbers of all anticipated user population(s) and all intended uses to give confidence that the overall residual risk determination is consistent with expectations. Any simulated use testing should be designed to provide similar levels of confidence. Unforeseen hazards that emerge from validation need to be assessed and, if necessary, controlled.

Note: Risk control measures need to be established and addressed prior to conducting clinical trials/investigations.

7.7. Control of design and development changes

History has repeatedly demonstrated that seemingly trivial changes may have unforeseen and sometimes catastrophic consequences. Proposed changes to the medical device and/or its manufacturing processes should be evaluated for their effect(s) on the safety of the device. This evaluation should be based on criteria for risk acceptability contained in risk management and design and development records and documents.

The need for changes may arise at any time in the life cycle of the medical device. Some of these changes can introduce new hazards, eliminate existing hazards, or change the level of risk associated with a hazard. A change could be the result of many factors, including a change in a risk control measure or a re-evaluation of the original risk assessment. If a change takes place, the current risk assessment should be reviewed and updated as necessary.

Examples of such changes are:

- A change of material (even nominally identical material from a different supplier);

- Replacement of one machine in a process by another;
- Seemingly trivial changes to a process may have cumulative effects;
- Change of suppliers;
- Change made by suppliers;
- Change of intended use or the intended user;
- When a device is part of a system and any single characteristic of the device or system changes, the system as a whole should be evaluated.

Prior to implementing a proposed change, it is important to ensure that any individual residual risk(s), as well as the overall residual risk, are defined and remain acceptable.

7.8. Design and development transfer

During design transfer the manufacturer should ensure the implementation and effectiveness of defined risk control measures. The manufacturer should ensure that existing or newly identified risk-related issues are resolved prior to the release of the design to production.

8. Traceability:

Risk management data should be utilized to define which devices, components, materials and work environment conditions require traceability.

Risk management activities should be used in conjunction with regulatory requirements to establish criteria for traceability. Points to be considered include:

- Origin of components and materials;
- Processing history;
- Distribution and location of the device after delivery (to the first consignee);
- Intended use of the device (i.e., life sustaining, life supporting, or implantable);
- Probability of failure;
- Need for safety related updates (i.e. recalls, advisory notices, field updates, etc.);
- Consequence of the failure for patients, users or other persons.

In defining the records required for traceability, the manufacturer should consider all those devices, components, materials and work environment conditions, which could cause the medical device not to satisfy its specified requirements including its safety requirements.

9. Purchasing Controls and Acceptance Activities:

9.1. Purchasing Controls

Risk management activities should identify hazards and evaluate risks, including those potentially introduced by suppliers early in the product realization process.

Risk management roles and responsibilities of the manufacturer and supplier should be defined as part of the purchasing requirements. In addition, prescribed risk control measures derived from the risk management process during product realization should be included in the purchasing requirements as part of the purchasing information.

Established criteria for selection, evaluation and re-evaluation of suppliers of purchased products and services should also be based upon the risk associated with identified hazards related to the purchased products and services determined during the risk management process.

9.2. Acceptance Activities

The manufacturer should communicate risk management policies, as well as establish and implement procedures necessary for ensuring that purchased product and services meet specified purchase requirements. In developing the acceptance criteria for purchased product and services, results of risk management activities should be considered. Specifically, the identified hazards and their related risk control measures need to be taken into account when developing criteria for verification and acceptance activities.

10. Production and Process Controls

The manufacturing process may be a source of identified hazards. These hazards can come from equipment, processes, work environment, personnel, etc., or the variability of those. These hazards should have already been identified during the design and development or are discovered during production or post-production. The risk control measures necessary to address these hazards need to be included in documented production and process control procedures.

The outcome of risk management activities may provide input to the development of appropriate methods for measuring and monitoring manufacturing processes. It is important for all personnel involved to understand the significance as well as the implementation of any risk control measures on the manufacturing processes to ensure the effectiveness of the risk control measures.

Risk assessment of manufacturing processes, using tools such as Hazard Analysis and Critical Control Points (HACCP), Hazard and Operability Study (HAZOP), Fault Tree Analysis (FTA), Failure Modes Effect Analysis (FMEA), Process Analytical Technology (PAT), etc., can help establish or improve process controls by identifying:

- What can go wrong at each step of the process;
- The impact of failure on the medical device;
- The likelihood of the failures; and,
- Controls to detect and prevent the failure or causes.

Production information such as the rate of nonconformities, the rate of rework, scrap, yield, and other sources of quality data should be evaluated and or compared against the current risk management output to confirm adequacy and completeness of risk controls.

10.1. Manufacturing, Measuring and Monitoring Equipment

Establishment of the suitability of equipment and the frequency of cleaning, maintenance and calibration should be considered with reference to the risks associated with the process.

Work instructions should also be reviewed and updated to reflect any appropriate risk control measures.

10.2. Work Environment and Personnel

Where the work environment or the impact of personnel on the medical device or process are determined to result in risk for the products or process, then risk control measures should be defined, documented and implemented. The effectiveness of these risk control measures should be periodically assessed.

10.3. Process Validation

Process validation and the determination of the need for revalidation may be influenced by the results of risk management activities. When performing process validation, risk management tools, such as FTA, FMEA, HAZOP, HACCP, PAT, or others, should be considered. Results of process validation or revalidation may identify the need for additional risk control measures. One example may be confirming or refining specific process parameters and controls when the source of an identified hazard is process variability.

When process changes are undertaken, current risk control measures should be reviewed for suitability. This review should also ensure that no new hazards were introduced.

11. Servicing

“Servicing” as used in this clause means repair and maintenance activities for medical devices.

When servicing is a specified requirement, information from risk management activities should be considered. Periodic servicing and maintenance as a means to ensure safe functioning of a device can be a method of risk control.

If a certain risk control measure is necessary for a production process, it may also be necessary to apply the same (or similar) risk control measure to the servicing process.

When there is a hazard to service personnel, clear instructions need to be included in servicing manuals or documentation and appropriate training provided.

12. Analysis of Data

Production and post-production information on the manufacturer’s own devices needs to be continually monitored and analyzed in performing new risk assessments and revising current risk assessments in order to maintain an effective risk management process.

Additional sources of information to be considered include:

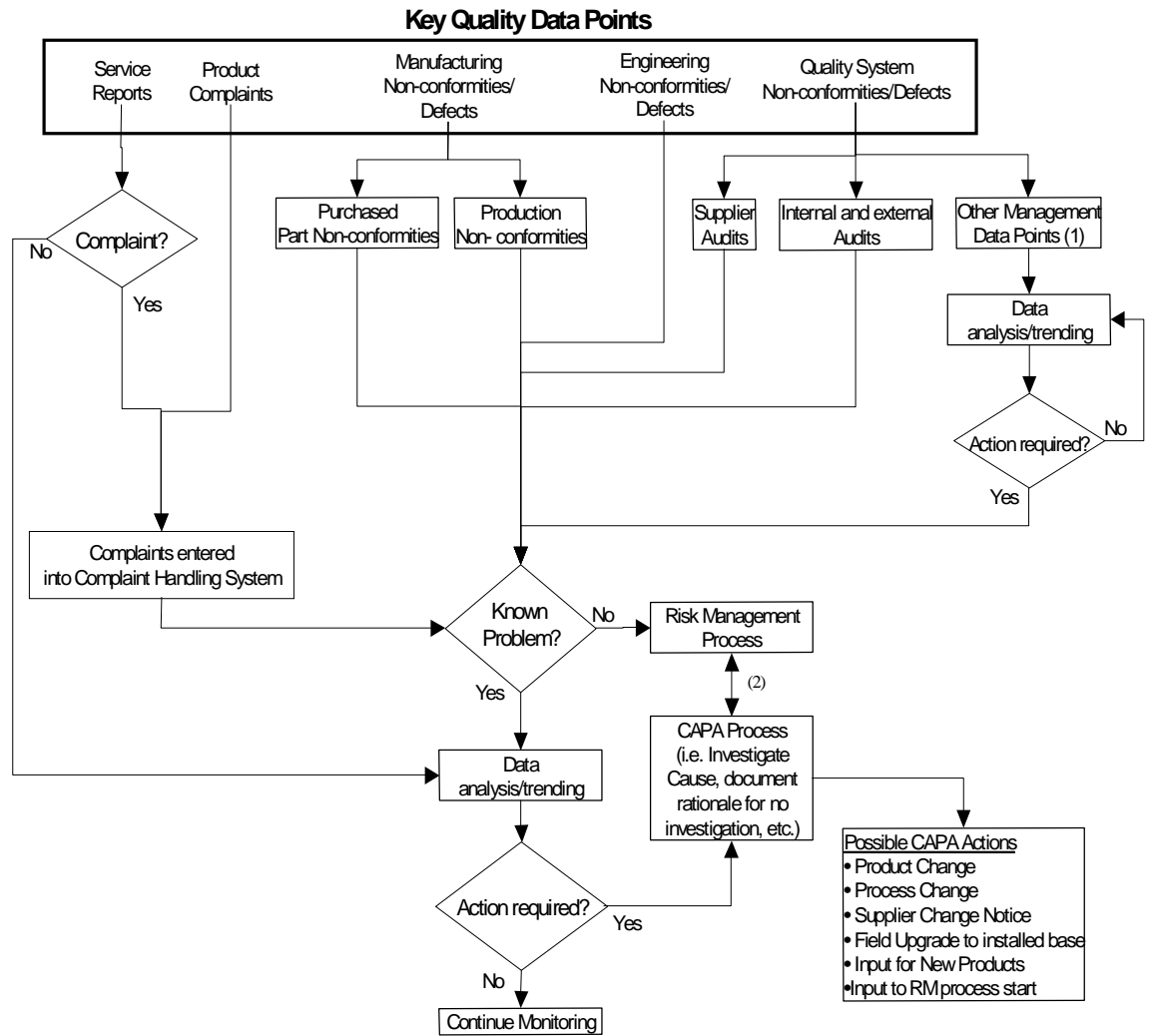
- Information on competitor’s devices;
- Information on similar medical devices on the market;
- Published information (recalls, Medical Device Reports, vigilance reports, etc.);

- Scientific literature.

The analysis of data should demonstrate that the decisions and risk control measures determined within the risk management process are appropriate.

13. Corrective and Preventive Actions (CAPA):

Figure 1 illustrates how risk management can be integrated into the CAPA process.



(1) Such as Finished Goods Returned, Credit restock
 (2) The relationship will depend upon the output of the investigation. This process can be iterative

Figure 1

The results of CAPA reviews should reveal any previously unrecognized risks and the effectiveness of risk control measures. This information should also be utilized to determine the effectiveness of the risk management activities and determine required actions to be taken to correct the identified issues and prevent recurrence.

For example, a service report indicating a safety related issue with a device is reported to a manufacturer and is determined to be a complaint. The complaint is reviewed and an investigation is initiated. During the investigation, it was determined that a manufacturing process change had occurred. Potential causes:

- Unanticipated effect on the device;
- Inadequate assessment of the process change;
- Inadequate revalidation;
- Lack of revalidation;
- Inadequate risk control measures;
- Risk control measures not evaluated with the change;

For any combination of the above, it is expected that the risk management system use this post market information to initiate another design risk assessment. The extent of the revised risk assessment will depend upon the complaint investigation results. The results of any revised risk assessment should be documented. Any new or revised risk control measures will be part of the overall CAPA activities.

Annex A: An Example of a Risk Chart for Communicating Internal Risk Management Activities

An effective and efficient risk management process requires a manufacturer to interpret risk consistently when conducting risk management activities. Certain standards provide simple and useful risk descriptions.

For example, the risk could be presented in a simple two-dimensional chart. Identified severity and occurrence categories are defined and justified. A manufacturer may define a three-region risk chart as follows:

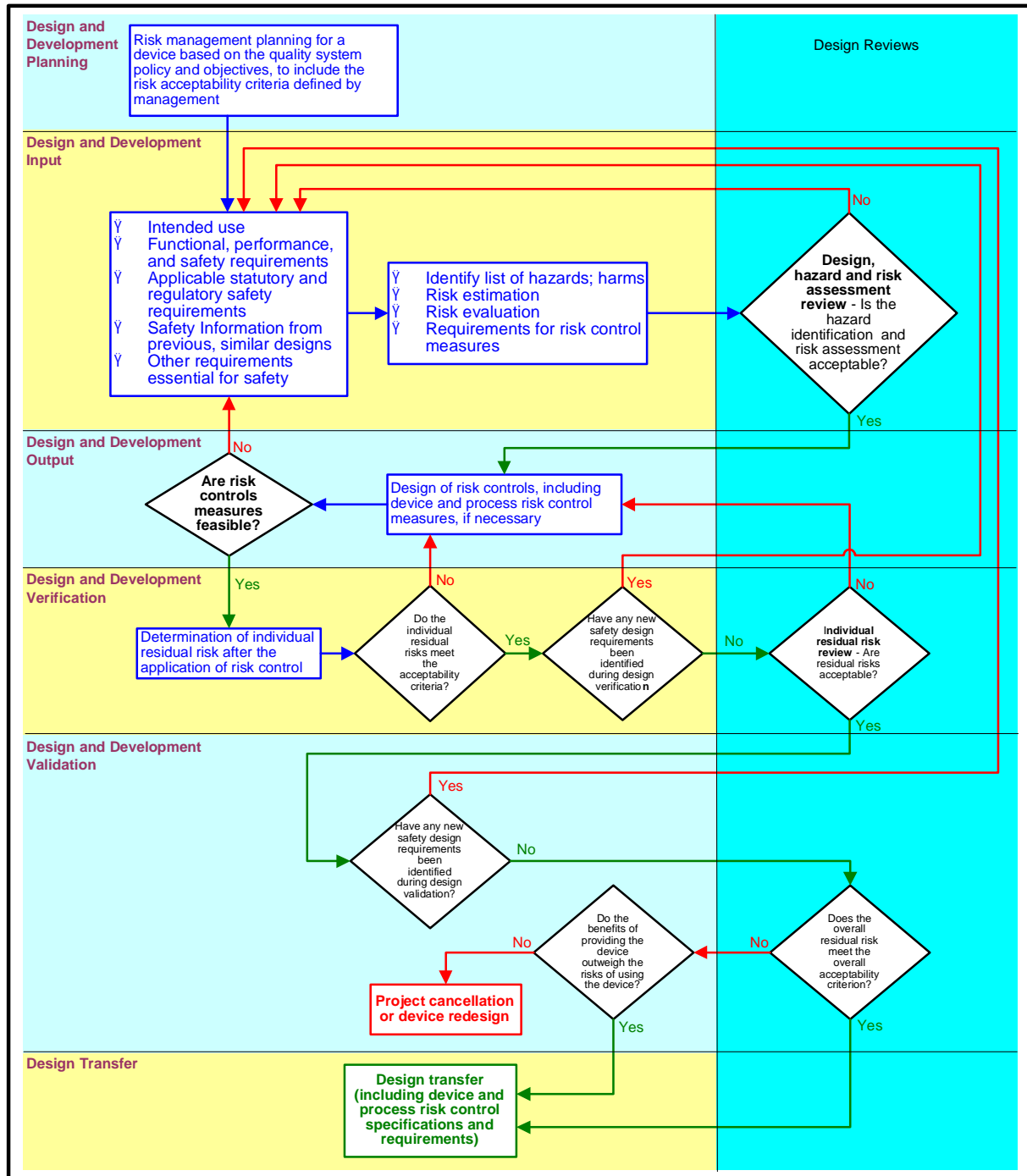
| | | | | | | |
|-----------------------------------|-----|-------------------------|------------|---------------|-------------|-----|
| Probability of Occurrence of Harm | O-6 | | | | | |
| | O-5 | | | | | |
| | O-4 | | | | HIGH | |
| | O-3 | | | MEDIUM | | |
| | O-2 | | LOW | | | |
| | O-1 | | | | | |
| | O-0 | | | | | |
| | | S-1 | S-2 | S-3 | S-4 | S-5 |
| | | Severity of Harm | | | | |

Legend

| Severity of Harm | | Probability of Occurrence of Harm | |
|------------------|--------------|-----------------------------------|---------------|
| S-5 | Catastrophic | O-6 | Always |
| S-4 | Critical | O-5 | Frequent |
| S-3 | Serious | O-4 | Probable |
| S-2 | Minor | O-3 | Occasional |
| S-1 | Negligible | O-2 | Remote |
| | | O-1 | Improbable |
| | | O-0 | None Observed |

Such a risk chart could be used as a communication tool among appropriate personnel.

Annex B: Flow Chart – Risk Management Activities in Design and Development



Note: While it is not possible to depict the iterative nature of processes within this flowchart, manufacturers should anticipate subsequent processes feeding back into prior process steps.

Annex C: Example of a Risk Management Summary Table

The following is just one example of how risk management activities can be documented. However, manufacturers may choose many different techniques by which to document or summarize risk management activities in a traceable manner. The summary table in Figure 3 provides a reasonable basis for quickly identifying the supporting documentation of the risk management activities.

Figure 3 shows an excerpt of a risk management summary table for a hypothetical infusion pump. Following is a description of the structure of the table.

| HazID (A) | Contributing Factors (A) | Risk level before applying risk control (B) | Risk level after applying risk control (B) | Risk Control Measure(s) (C) | RqtID (D) | TestID (D) | Status (E) |
|---------------------------|--|--|---|--|---------------------|-----------------------|---------------|
| 3.0 Dosage Hazards | | | | | | | |
| 3.1 Overdose | | | | | | | |
| 3.1.1 | User setup error | I-B | I-D | a) Alphanumeric display shows delivery rate and units | HRD 4.5.2 | STP 3.5 | Pass |
| | | | | b) (Barcode Option) Delivery rate encoded in prescription barcode; user prompted to scan patient bracelet and confirm settings | HRD 8.3 SRD 12.6 | STP 22.1 thru 22.5 | Pass |
| 3.1.2 | Tampering with settings | I-B | I-D | Keyboard lock prevents unauthorized setting change | SRD 7.2 | STP 17 | Awaiting test |
| 3.1.3 | Pump over-run due to microprocessor lockup | I-B | II-D | a) Blocking capacitor limits pump on time to a maximum of one second | HRD 9.2 | STP 32.0 | Pass |
| | | | | b) Watchdog timer interrupts power to pump | HRD 10.5 | STP 26.2 | Pass |
| 3.2 Under-dose | | | | | | | |
| . | | | | | | | |
| . | | | | | | | |

Figure 3: Risk Management Summary Table Excerpt

A. Hazard Identification (HazID)

In this example (which is a different method from that illustrated in Annex A), risks are identified using a three-level hierarchy. The top level of the hierarchy reflects the major classes of hazards. For example, in an infusion pump, some of the major classes of hazards might include:

- 1.0 Energy hazards
- 2.0 Mechanical hazards
- 3.0 Dosage hazards

The second level of hazard classification identifies particular hazards. For example, in an infusion pump, two hazards related to dosage are:

- 3.1 Overdose
- 3.2 Under-dose

The third level of hazard classification is a particular cause or contributing factor. Typically, a given hazard may have multiple causes or contributing factors, combinations of which lead to similar outcomes, as shown in the example.

B. Risk Evaluation

These two columns show the results of risk evaluation before and after risk control. In this example, the risk level is characterized by a coding scheme using Roman numerals and letters to denote estimates for severity and likelihood, respectively. The color or shading of the cell represents the manufacturer's grading of risk acceptability (e.g., intolerable, undesirable, tolerable, negligible). The details of the scheme used by this manufacturer are not important for this example. Other manufacturers may employ different approaches to risk evaluation, but the results in any case would be summarized in these two columns.

C. Risk Control Measures

This column describes the risk control measures that form the basis for the risk reduction shown. The actual risk scenarios and risk control measures might be far more complex than is possible to describe in a short summary paragraph. In that case, the entry in this column might refer to another document that describes the risk control measures in more detail.

D. Traceability Data (RqtID and TestID)

These two columns provide traceability between risk control measures, device design requirements, and verification/validation activities. The column labeled "Requirement Identification" (RqtID) points to relevant clauses in the medical device design documentation that define requirements relating to a given risk control measure. The column labeled "Test Identification" (TestID) points to clauses in test procedures or other verification and validation documents that confirm that the control measure was adequately implemented.

In the example, "HRD" refers to the device's Hardware Requirements Document, and "SRD" refers to the Software Requirements Document. "STP" refers to the System Test Procedure for this particular device.

E. Status Information

The last column is used during medical device development to track progress in completing risk management activities. This example uses cell color or shading to highlight incomplete activities.

Example of Use of the Table

As an example of how to use the risk management summary table, consider the entry for HazID 3.1.2. This entry describes the use of a keyboard lock to prevent unauthorized changes to device settings. The keyboard lock mechanism, as a risk control measure, was judged to reduce risk from a level of I-B to I-D, reflecting reduced likelihood of the hazardous event. The requirement for a keyboard lock was captured in the Software Requirements Document, paragraph 7.2, and the functionality of the keyboard lock was tested in Section 17 of the System Test Procedure. The last column indicates that the results of this testing are not yet available.

Literature

- ISO 9000:2000** Quality management systems – Fundamentals and vocabulary
- ISO 13485:2003** Medical devices – Quality management systems – System requirements for regulatory purposes
- ISO 14971:2000** Medical devices – Application of risk management to medical devices
- IEC 62366 Ed. 1** Medical Devices – General requirements for safety and essential performance-Usability
- IEC 60601-1-6:2004** Medical Electrical Equipment – Part 6: General Requirements for safety - Usability
- General Principles of Software Validation;** Final Guidance for Industry and for FDA Staff (FDA/CDRH, issued January 11, 2002)
<http://www.fda.gov/cdrh/comp/guidance/938.html>
- Off-The-Shelf Software Use in Medical Devices;** Guidance for Industry, FDA Reviewers and Compliance on (FDA/CDRH, issued on September 9, 1999)
<http://www.fda.gov/cdrh/ode/guidance/585.html>
- Do It By Design - An Introduction to Human Factors in Medical Devices;** (FDA/CDRH, issued December 1996)
<http://www.fda.gov/cdrh/humfac/doi.html>

Also Consider These Draft Documents and Resulting Final Documents:

- IEC/1CD 62304** Medical device software - Software life-cycle processes (Developed by IEC/SC 62A and ISO/TC 210 JWG 3, date of circulation 2003-01-17, closing dates for comments 2003-04-21)
- ISO/DTS2 19218** Medical Devices - Coding structure for event type and cause

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